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PATENT **A**
Date: March 30, 2000
File No.: 1506.63818

Sir:

Transmitted herewith for filing is the patent application of

Inventor(s): Douglas W. Morck and
Simon P. Holland

For: METHOD AND APPARATUS FOR
REDUCING OUTBREAKS OF
DIFFUSE LAMELLAR KERATITIS

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March 30, 2000

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jc682 U.S. PTO
09/53821
03/30/00

Enclosed are:

- (X) 19 pages of specification, including 37 claims and an abstract.
(X) an executed oath or declaration, with power of attorney.
() an unexecuted oath or declaration, with power of attorney.
() sheet(s) of informal drawing(s).
(X) 4 sheet(s) of formal drawings(s).
() Assignment(s) of the invention to _____
() Assignment Form Cover Sheet.
() A check in the amount of \$_____ to cover the fee for recording the assignment(s).
() Information Disclosure Statement.
() Form PTO-1449 and cited references.
(X) Associate Power of Attorney.
() Priority Document.

Fee Calculation For Claims As Filed

a) Basic Fee					\$ 690.00
b) Independent Claims	7	- 3	= 4	x \$ 78.00	= \$ 312.00
c) Total Claims	37	- 20	= 17	x \$ 18.00	= \$ 306.00
d) Fee for Multiple Claims				\$260.00	= \$ _____

Total Filing Fee \$ 1308.00

- (X) 1 Statement(s) of Status as Small Entity, reducing filing fee in half to \$ 654.00
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() Charge \$_____ to Deposit Account No. 07-2069.
(X) Other Preliminary Amendment
(X) The Commissioner is hereby authorized to charge any additional fees which may be required to this application under 37 C.F.R. §§1.16-1.17, or credit any overpayment, to Deposit Account No. 07-2069. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 07-2069. Two duplicate copies of this sheet are enclosed.

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GREER, BURNS & CRAIN, LTD.

By: 

Roger D. Greer

Registration No. 26,174

Applicant or Patentee: Douglas W. Morck and Simon P. Holland
Serial or Patent No.: _____ Attorney's Docket No.: M509 0002
Filed or Issued: herewith
For: METHOD AND APPARATUS FOR REDUCING OUTBREAKS OF DIFFUSE LAMELLAR KERATITIS

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 C.F.R. 1.9(f) and 1.27(b)) -- INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled METHOD AND APPARATUS FOR REDUCING OUTBREAKS OF DIFFUSE LAMELLAR KERATITIS

described in:

☒ the specification filed herewith

☐ application Serial No. _____ filed _____

☐ Patent No. _____ issued _____

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a non-profit organization under 37 C.F.R. 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey or license, any rights in the invention is listed below:

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☒ persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. 1.27)

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☐ Individual ☒ Small Business Concern ☐ Non Profit Organization

I acknowledge my duty to file, in this application, or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such wilful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Inventor

Name of Inventor

Name of Inventor

Inventor's Signature

~~Inventor's Signature~~

Inventor's Signature

Date _____

Date _____

Date _____

[illegible]

1506.63818

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Douglas W. Morck and
Simon P. Holland

Serial No.:

Filed: March 30, 2000

For: METHOD AND APPARATUS FOR
REDUCING OUTBREAKS OF
DIFFUSE LAMELLAR KERATITIS

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PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of this application, please amend the application as
follows:

In The Claims:

Please amend claim 33 as follows:

33. (amended) A method for reducing outbreaks of diffuse lamellar keratitis
comprising carrying out [the] a first method [of claim 13] on a daily basis and [the] a second
method [of claim 17] on a less frequent basis;

said first method comprising a method for reducing outbreaks of aseptic
inflammations of the eye resulting from eye surgery in eye surgery clinics using a sterilizer
for sterilizing medical instruments with steam comprising a housing containing a steam
generator supplied by a dispensing pump and a sterilization container for containing said

medical instruments, and further comprising a reservoir of distilled water which holds and supplies distilled water to be boiled for the sterilization, said first method comprising:

i) at the start of a surgery day carrying out the following procedures on a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and a sterilization container for containing said medical instruments, and further comprising a reservoir which can be emptied by a pump, within said housing for receiving distilled water and which holds and supplies distilled water to be boiled for the sterilization:

1. Fill the empty reservoir with boiling tap water and drain using said pump;
2. Repeat step 1;
3. Rinse the reservoir by filling with distilled water and drain with said pump;
4. Repeat step 3;
5. Repeat step 3;
6. Prepare and conduct the first sterilization run of instruments.

ii) at the end of the surgery day carrying out the following procedures on said sterilizer

1. Drain the sterilizer reservoir with said pump;
2. Fill the reservoir with boiling water and scrub the entire inner surface of the reservoir with a clean brush;
3. Drain the reservoir with said pump;
4. Fill the reservoir with boiling water and scrub the entire inner surface of the reservoir, again with a clean brush;
5. Drain the reservoir with said pump;
6. Rinse the reservoir by filling and draining the reservoir three (3) times with distilled water;

7. Fill the reservoir with a solvent solution and scrub the inner surface of the reservoir with a clean brush;
8. Drain the reservoir with said pump;
9. Rinse the reservoir by filling and draining the reservoir three (3) times with distilled water;
10. Dry the inside of the reservoir;
11. Store the reservoir empty and allow to dry;

said second method comprising a method for reducing outbreaks of aseptic inflammations of the eye resulting from eye surgery in eye surgery clinics using a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and a sterilization container for containing said medical instruments, and further comprising a reservoir of distilled water which holds and supplies distilled water to be boiled for the sterilization, said second method comprising:

i) periodically carrying out the following procedures on a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and a sterilization container for containing said medical instruments, and further comprising a reservoir within said housing for receiving distilled water and which holds and supplies distilled water to be boiled for the sterilization:

1. Fill the empty reservoir with boiling tap water, add disinfectant, and scrub all of the inner surface of the reservoir using a clean brush; and drain using said pump;
2. Repeat step 1 three more times;
3. Fill the reservoir with boiling tap water and drain using said pump;
4. Repeat step 3 two more times;
5. Rinse the reservoir by filling with distilled water and drain with the pump.
6. Repeat step 5 two more times;
7. Fill the reservoir with a solvent solution and scrub the inner surface of the

reservoir with a clean brush;

8. Drain the reservoir with said pump;

9. Rinse the reservoir by filling and draining the reservoir three times with distilled water;

10. Dry the inside of the reservoir;

11. Store the reservoir empty and dry overnight;

12. Change the rubber tube inside the reservoir periodically.

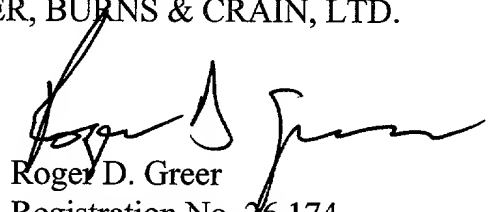
REMARKS

Applicant respectfully requests that these amendments to the claims be considered with the examination of this application.

Respectfully submitted,

GREER, BURNS & CRAIN, LTD.

By


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**METHOD AND APPARATUS FOR REDUCING OUTBREAKS OF
DIFFUSE LAMELLAR KERATITIS**

Technical Field

5

The invention relates to methods and apparatus for sterilization of ophthalmological instruments, and more particularly to sterilization methods and apparatus for reducing outbreaks of diffuse lamellar keratitis.

10 **Background Art**

Diffuse lamellar keratitis or DLK (also referred to as "Sands of the Sahara keratitis") is a recently recognised post-surgical condition involving an inflammation that occurs in laser corneal surgery patients. This condition is typically associated with the

15 LASIK surgical procedure (Laser Assisted In Situ Keratomileusis), the most rapidly increasing laser corneal surgery procedure in North America. It usually occurs in the first few days postoperatively. In LASIK surgery, surgeons cut a flap of the cornea and fold it back to expose the layer below, which is shaped with the laser to correct the patient's vision. The corneal flap is then put back in place. The DLK condition, an

20 inflammatory infection, can develop under the corneal flap and can threaten the patient's sight. DLK usually responds to intensive topical steroids, with lifting of the flap and irrigation in more advanced stages. Untreated or severe cases may progress to melting of the flap with the potential for significant loss of vision. It can occur at low levels in some surgical clinics, however, massive outbreaks have also occurred, where 30-80%

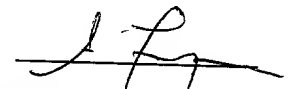
25 of patients receiving the surgical procedure at a clinic may be affected. To date the cause of the complication is not known. Some authors have suggested deposits from the microkeratome blade as a cause of DLK. Others relate DLK to particles from the eye drape. Since the use of laser surgery to correct vision is a relatively new technique which is seeking to be generally accepted, it is important that outbreaks of this

30 inflammation be prevented or at least minimized.

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Disclosure of Invention

The present inventors have discovered a method and apparatus to reduce outbreaks of the DLK inflammation. Instrument sterilizers are used to prepare surgical materials for the LASIK procedure. These sterilizers have a holding tank, or reservoir, that supplies water to be turned into steam for the sterilization. If these holding tanks become contaminated with specific biofilm bacteria they can become a source of certain toxins (lipopolysaccharide or endotoxin) that can be released into the sterilizer system and deposited on the surgical instruments that are to be used in the delicate structures of the eye (corneal stroma). These toxins are extremely heat stable (400°F for 4 hours is required to destroy them) therefore they are not destroyed by the short sterilization cycles provided by the sterilizers in these surgical clinics. As a result of this it is imperative to remove these biofilm bacteria from the reservoirs and to keep the reservoirs free of subsequent contamination by biofilm bacteria.

The present invention therefore provides a method to remove biofilm bacteria from the reservoirs in these sterilizers, a method to prevent biofilm bacteria from contaminating the reservoirs, and an external reservoir that may be fitted on existing sterilizers, by-passing the existing internal reservoirs, that is simple to use and on which it is very easy to conduct preventative anti-biofilm procedures.

Brief Description of Drawings

In drawings which illustrate a preferred embodiment of the invention:
Fig. 1 is a front perspective view of the existing sterilization equipment;
Fig. 2 is a rear perspective view of the existing sterilization equipment modified according to the invention;

Fig. 3 is a front view of the water reservoir used in the sterilization equipment modified according to the invention; and

Fig. 4 is a rear perspective view of a further embodiment of the invention;

5 Best Mode(s) For Carrying Out the Invention

Currently in laser eye surgery, instrument sterilizers are used to sterilize the surgical instruments for the LASIK procedure between each patient. Since a rapid rate of sterilization is required due to high patient turnover, the preferred sterilizers have been
10 autoclaves used previously in dental practices, as illustrated in Fig. 1, designated generally by reference numeral 10. For example, the preferred and widely used sterilizer is the STATIM™ cassette autoclave manufactured by SciCan Division of Lux and Zwingenberger Ltd., and in particular the STATIM 5000™. Such a sterilizer is described in U.S. patent no. 5,271,893 - Newman issued December 21, 1993. Another
15 commonly used sterilizer is the AMSCO Eagle 10™ manufactured by Steris of Mentor, Ohio. These sterilizers have a 4 to 10 minute sterilization cycle and use steam injection to achieve sterilization. They typically have an internal holding tank, or reservoir 12 within housing 11, lined with plastic and having an irregular surface, which holds and supplies distilled water to be heated for the sterilization. The distilled water flows, by
20 pump or gravity feed, through rubber tubing to a dosing pump 13 and a steam generator or boiler unit 14, which provides steam under pressure to the cassette 16 in which the surgical instruments to be sterilized are placed. In more recent models, an air pump (not shown) pumps the distilled water through an external, replaceable filter 19, prior to its injection into the boiler unit 14.

25 The present inventors believe that endotoxins released from gram negative bacterial biofilms in sterilizer reservoirs may be the cause of outbreaks of DLK. The irregular plastic surfaces of the reservoirs are ideal for bacterial biofilm development and if the holding tanks 12 become contaminated with specific biofilm bacteria they can become a source of certain toxins (lipopolysaccharide or endotoxin) that can be released

into the sterilizer system and deposited on the surgical instruments that are to be used in the delicate structures of the eye (corneal stroma). These toxins are extremely heat stable (can withstand up to 400°F for 4 hours) therefore they are not destroyed by the short sterilization cycles provided by the sterilizers in these surgical clinics. As a result of this
5 it is imperative to remove these biofilm bacteria from the reservoirs and to keep the reservoirs free of subsequent contamination by biofilm bacteria. The present invention therefore is a methodology to remove biofilm bacteria from the reservoirs in these sterilizers and to prevent biofilm bacteria from contaminating the reservoirs. Further, the inventors have also developed a special external reservoir that may be retro-fitted to
10 existing sterilizers, by-passing the existing internal reservoirs, that is simple to use and on which it is very easy to conduct preventative anti-biofilm procedures.

Investigations of certain outbreaks of DLK show similar features in support of the endotoxin-outbreak DLK theory. In a first case *Burkholderia pickettii* was isolated from the sterilizer reservoir; in a second case *Burkholderia (Pseudomonas) cepacia* was
15 isolated from the STATIM™ sterilizer reservoirs and from a tabletop distiller. The outbreak was brought under control by using similar methods to those described herein, to disinfect the sterilizer reservoir. All cases were related to sterilizer reservoir contamination with a *Burkholderia* or *Pseudomonas* species. After implementing the control measures described herein the attack rate of DLK was significantly reduced.

20

A. Sterilizer modification

A separate, removable re-usable reservoir 20 (Fig. 2 and 3) is provided for storing sterile, endotoxin free distilled water. Preferably it is manufactured from a
25 substance which can be subjected to sufficiently high temperatures to destroy endotoxins, preferably Pyrex™ glass or stainless steel. It has a threaded neck 22, and a polished lip 24, to receive a threaded stainless steel cap 26 sealed with O-ring 28 and provided with a nipple 30 to which biotechnology grade silicon tubing 32 is connected to feed distilled water directly to the heating unit 14 of sterilizer 10. Tubing 32 may be either disposable

or re-usable. The reservoir 20 is provided with an air release valve 34 which is opened when the reservoir is inverted and the system operating to provide air pressure for the gravity feed. The reservoir 20 is preferably wall-mounted on a mounting bracket 21 and easily removable so that its inside surfaces can be scrubbed and subjected to long periods of high temperature.

According to an alternate embodiment, a disposable external reservoir may be used in place of reservoir 20. This may be a commercially available bag or bottle of sterile endotoxin-free (non-pyrogenic) distilled water used for irrigation similar to those used for bags or bottles for intravenous fluids for patient use. Suitable disposable bags/bottles of sterile endotoxin-free (non-pyrogenic) distilled water are available from Baxter Corp., Abbott Laboratories, and others. The disposable external reservoir may be directly attached to the water supply line of existing models of sterilizer units such as the STATIM[™], as described above for the re-usable reservoir 20, but when empty the disposable reservoir is simply disposed and replaced.

According to yet another alternate embodiment, a disposable, removable internal reservoir 40 (shown in dotted outline in Fig. 4) may be used in place of reservoir 12 inside the housing 11 of sterilizer 10. This may be a container made of, or lined with high density polyethylene (HDPE) or similar plastic. The disposable removable reservoir is previously filled with sterile endotoxin-free (non-pyrogenic) distilled water, or it can be filled after insertion into the housing 11 through a closable opening 42 in the container. The reservoir is inserted into an appropriately sized cavity in sterilizer housing 11 through a closable opening 42 in housing 11 and directly attached to the water supply line for the sterilizer 13/14 by means of disposable SILASTIC[™] tubing. The removable reservoir 40 and attached tubing is removed, disposed of and replaced periodically, depending on the amount of use, to avoid build-up of biofilm and endotoxins. Typically this will be on a weekly basis.

The foregoing removable reservoir 20, whether reusable or disposable, can be manufactured as part of a new sterilizer of the STATIM[™] type. or retrofitted to existing sterilizers. Where the sterilizer has an external filter 19, as shown in Fig. 2, or where

there is no external filter 19, the output tubing 32 from the reservoir 20 is connected to the line 34 leading from holding tank 12 to the boiler unit 14. It may be necessary to cut a hole 33 in the sterilizer casing to allow access of output tubing 32 to the input to the boiler unit 14. Alternatively, the sterilizer may be manufactured without the internal
5 reservoir 12 but rather with a built-in tubing connection to the external removable reservoir 20.

Where it is not desirable or possible to provide a removable reservoir as noted above, the following methods have been found to control DLK outbreaks. These involve first a system of draining the sterilizer at the end of each surgical day and using
10 mechanical scrubbing and boiling water treatments in the morning prior to and at the end of each surgical day. At longer intervals, an isopropyl alcohol solution at about 70% was also placed in the sterilizer at the end of the surgical day, allowed to evaporate and then the boiling water treatment performed. These methods are considered unlikely to damage the polymer lining.

15

B. Sterilizer Maintenance Procedure

This method is carried out on a daily basis as follows:

i) Start of the Surgery Day

20

1. Fill the empty reservoir with boiling tap water and drain using the sterilizer's pump.
2. Fill the reservoir with boiling tap water and drain using the pump.
3. Rinse the reservoir by filling with room temperature distilled water and drain with the pump.
- 25 4. Rinse the reservoir by filling with room temperature distilled water and drain with the pump.
5. Rinse the reservoir by filling with room temperature distilled water and drain with the pump.
6. Prepare and conduct the first sterilization run of instruments.

ii) End of the Surgery Day

1. Drain the sterilizer reservoir with the pump.
2. Fill the reservoir with boiling water and scrub the entire inner surface of the reservoir
5 with a clean brush.
3. Drain the reservoir with the pump.
4. Fill the reservoir with boiling water and scrub the entire inner surface of the reservoir,
again with a clean brush.
5. Drain the reservoir with the pump.
- 10 6. Rinse the reservoir by filling and draining the reservoir three (3) times with room
temperature distilled water.
7. Fill the reservoir with isopropyl alcohol (70%) and scrub the inner surface of the
reservoir with the rinsed clean brush.
8. Drain the reservoir with the pump.
- 15 9. Rinse the reservoir by filling and draining the reservoir three (3) times with room
temperature distilled water.
10. Dry the inside of the reservoir with hair dryer or wipe the inside of the reservoir dry
with a clean cloth.
11. Store the reservoir empty and dry overnight.
- 20 12. Change the rubber tube inside the reservoir weekly.

C. Major Sterilizer Clean up Procedure

This method is carried out on a less frequent basis, perhaps a quarterly basis (every 13
25 to 14 weeks).

1. Fill the empty reservoir with boiling tap water, add disinfectant (hypochlorite), and
vigorously scrub using the clean brush (15 minutes and the scrub must cover all of the
inner surface of the reservoir). Drain using the pump.

2. Fill the empty reservoir with boiling tap water, add disinfectant, and vigorously scrub using the clean brush (15 minutes and the scrub must cover all of the inner surface of the reservoir). Drain using the pump.
3. Fill the empty reservoir with boiling tap water, add disinfectant, and vigorously scrub using the clean brush (15 minutes and the scrub must cover all of the inner surface of the reservoir). Drain using the pump.
4. Fill the empty reservoir with boiling tap water, add disinfectant, and vigorously scrub using the clean brush (15 minutes and the scrub must cover all of the inner surface of the reservoir). Drain using the pump.
5. Fill the reservoir with boiling tap water and drain using the pump.
6. Fill the reservoir with boiling tap water and drain using the pump.
7. Fill the reservoir with boiling tap water and drain using the pump.
8. Rinse the reservoir by filling with room temperature distilled water and drain with the pump.
9. Rinse the reservoir by filling with room temperature distilled water and drain with the pump.
10. Rinse the reservoir by filling with room temperature distilled water and drain with the pump.
11. Fill the reservoir with isopropyl alcohol (70%) and scrub the inner surface of the reservoir with the very well rinsed clean brush.
12. Drain the reservoir with the pump.
13. Rinse the reservoir by filling and draining the reservoir three (3) times with room temperature distilled water.
14. Dry the inside of the reservoir with hair dryer or wipe the inside of the reservoir dry with a clean cloth.
15. Store the reservoir empty and dry overnight.
16. Change the rubber tube inside the reservoir weekly.

While the foregoing apparatus and methods have been found useful to reduce outbreaks of diffuse lamellar keratitis, they are also believed to be useful for reducing outbreaks of other aseptic inflammations of the eye resulting from eye surgery, such as sterile endophthalmitis.

- 5 While isopropyl alcohol (70%) has been identified as an appropriate agent in the foregoing process, other solvents such as ethanol, methanol and acetone would also be suitable.

- 10 As will be apparent to those skilled in the art in the light of the foregoing disclosure, many alterations and modifications are possible in the practice of this invention without departing from the spirit or scope thereof. Accordingly, the scope of the invention is to be construed in accordance with the substance defined by the following claims.

WHAT IS CLAIMED IS:

1. An apparatus for reducing outbreaks of aseptic inflammations of the eye resulting from eye surgery comprising a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and
5 a sterilization container for containing said medical instruments, and further comprising a reservoir of distilled water which holds and supplies distilled water to be boiled for the sterilization, wherein said reservoir is separable from said housing and manufactured from a substance which can be subjected to sufficiently high temperatures to destroy endotoxins.
10
2. The apparatus of claim 1 wherein said aseptic inflammation of the eye resulting from eye surgery is diffuse lamellar keratitis.
3. The apparatus of claim 1 wherein said aseptic inflammation of the eye resulting
15 from eye surgery is sterile endophthalmitis.
4. The apparatus of claim 1 wherein said reservoir is independent from said housing.
5. The apparatus of claim 1 wherein said reservoir is manufactured from
20 Pyrex glass.
6. The apparatus of claim 1 wherein said reservoir is manufactured from stainless steel.
- 25 7. The apparatus of claim 1 wherein said reservoir comprises a hollow vessel having a threaded neck to sealingly receive a threaded cap provided with means to receive a tubing for connecting said reservoir to said steam generating unit.

8. The apparatus of claim 1 wherein said reservoir is adapted to be inverted in use and is provided with an air release valve which is opened when the reservoir is inverted and the system operating.

5 9. The apparatus of claim 1 wherein said reservoir is a disposable external reservoir.

10. The apparatus of claim 1 wherein said reservoir is a disposable, removable internal reservoir adapted to be removably contained within the housing of sterilizer 10

10 11. The apparatus of claim 7 wherein said disposable external reservoir is a bag of
sterile endotoxin-free distilled water.

12. The apparatus of claim 7 wherein said disposable external reservoir is a bottle of sterile endotoxin-free distilled water.

15

13. A method for reducing outbreaks of aseptic inflammations of the eye resulting from eye surgery in eye surgery clinics using a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and a sterilization container for containing said medical instruments, and further comprising a reservoir of distilled water which holds and supplies distilled water to be boiled for the sterilization, said method comprising:

20

25 i) at the start of a surgery day carrying out the following procedures on a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and a sterilization container for containing said medical instruments, and further comprising a reservoir which can be emptied by a pump, within said housing for receiving distilled water and which holds and supplies distilled water to be boiled for the sterilization:

1. Fill the empty reservoir with boiling tap water and drain using said pump;
2. Repeat step 1;
3. Rinse the reservoir by filling with distilled water and drain with said pump;
4. Repeat step 3;
5. Repeat step 3;
6. Prepare and conduct the first sterilization run of instruments.

ii) at the end of the surgery day carrying out the following procedures on said sterilizer

1. Drain the sterilizer reservoir with said pump;
2. Fill the reservoir with boiling water and scrub the entire inner surface of the reservoir with a clean brush;
3. Drain the reservoir with said pump;
4. Fill the reservoir with boiling water and scrub the entire inner surface of the reservoir, again with a clean brush;
5. Drain the reservoir with said pump;
6. Rinse the reservoir by filling and draining the reservoir three (3) times with distilled water;
7. Fill the reservoir with a solvent solution and scrub the inner surface of the reservoir with a clean brush;
8. Drain the reservoir with said pump;
9. Rinse the reservoir by filling and draining the reservoir three (3) times with distilled water;
10. Dry the inside of the reservoir;
11. Store the reservoir empty and allow to dry.

14. The method of claim 13 wherein said aseptic inflammation of the eye resulting from eye surgery is diffuse lamellar keratitis.

15. The method of claim 13 wherein said aseptic inflammation of the eye resulting from eye surgery is sterile endophthalmitis.

16. The method of claim 13 wherein said solvent solution is selected from the group
5 isopropyl alcohol, ethanol, methanol and acetone.

17. A method for reducing outbreaks of aseptic inflammations of the eye resulting
from eye surgery in eye surgery clinics using a sterilizer for sterilizing medical
instruments with steam comprising a housing containing a steam generator supplied by
10 a dispensing pump and a sterilization container for containing said medical instruments,
and further comprising a reservoir of distilled water which holds and supplies distilled
water to be boiled for the sterilization, said method comprising:

15 i) periodically carrying out the following procedures on a sterilizer for sterilizing
medical instruments with steam comprising a housing containing a steam
generator supplied by a dispensing pump and a sterilization container for
containing said medical instruments, and further comprising a reservoir within
said housing for receiving distilled water and which holds and supplies distilled
water to be boiled for the sterilization:

20

1. Fill the empty reservoir with boiling tap water, add disinfectant, and scrub all
of the inner surface of the reservoir using a clean brush; and drain using said
pump;

2. Repeat step 1 three more times;

25

3. Fill the reservoir with boiling tap water and drain using said pump;

4. Repeat step 3 two more times;

5. Rinse the reservoir by filling with distilled water and drain with the pump.

6. Repeat step 5 two more times;

7. Fill the reservoir with a solvent solution and scrub the inner surface of the reservoir with a clean brush;
 8. Drain the reservoir with said pump;
 9. Rinse the reservoir by filling and draining the reservoir three times with distilled water;
 10. Dry the inside of the reservoir;
 11. Store the reservoir empty and dry overnight;
 12. Change the rubber tube inside the reservoir periodically.
- 10 18. The method of claim 17 wherein said aseptic inflammation of the eye resulting from eye surgery is diffuse lamellar keratitis.
- 15 19. The method of claim 17 wherein said aseptic inflammation of the eye resulting from eye surgery is sterile endophthalmitis.
- 20 20. The method of claim 17 wherein said procedures are carried out less frequently than a daily basis.
- 21 21. The method of claim 17 wherein said procedures are carried out on a quarterly basis.
- 22 22. The method of claim 17 wherein said solvent solution is selected from the group isopropyl alcohol, ethanol, methanol and acetone.
- 25 23. A method for reducing outbreaks of aseptic inflammations of the eye resulting from eye surgery in eye surgery clinics using a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and a sterilization container for containing said medical instruments,

and further comprising a reservoir of distilled water which holds and supplies distilled water to be boiled for the sterilization, said method comprising:

5 i) at the start of a surgery day carrying out the following procedures on a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and a sterilization container for containing said medical instruments, and further comprising a reservoir which can be emptied by a pump, within said housing for receiving distilled water and which holds and supplies distilled water to be boiled for the sterilization:

10

1. Fill the empty reservoir with boiling tap water and drain using said pump;
2. Rinse the reservoir by filling with distilled water and drain with said pump;
6. Prepare and conduct the first sterilization run of instruments.

15

ii) at the end of the surgery day carrying out the following procedures on said sterilizer

20

1. Drain the sterilizer reservoir with said pump;
2. Fill the reservoir with boiling water and scrub the entire inner surface of the reservoir with a clean brush;
3. Drain the reservoir with said pump;
4. Rinse the reservoir by filling and draining the reservoir three (3) times with distilled water;
5. Fill the reservoir with a solvent solution and scrub the inner surface of the reservoir with a clean brush;
- 25 6. Drain the reservoir with said pump;
7. Rinse the reservoir by filling and draining the reservoir three (3) times with distilled water;
8. Dry the inside of the reservoir;

25

9. Store the reservoir empty and dry overnight.

24. The method of claim 23 wherein said aseptic inflammation of the eye resulting from eye surgery is diffuse lamellar keratitis.

5

25. The method of claim 23 wherein said aseptic inflammation of the eye resulting from eye surgery is sterile endophthalmitis.

26. The method of claim 23 wherein said solvent solution is selected from the group
10 isopropyl alcohol, ethanol, methanol and acetone.

27. A method for reducing outbreaks of aseptic inflammations of the eye resulting from eye surgery in eye surgery clinics using a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by
15 a dispensing pump and a sterilization container for containing said medical instruments, and further comprising a reservoir of distilled water which holds and supplies distilled water to be boiled for the sterilization, said method comprising:

20 i) periodically carrying out the following procedures on a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and a sterilization container for containing said medical instruments, and further comprising a reservoir within said housing for receiving distilled water and which holds and supplies distilled water to be boiled for the sterilization:

25

1. Fill the empty reservoir with boiling tap water, add disinfectant, and scrub all of the inner surface of the reservoir using a clean brush; and drain using said pump;

2. Fill the reservoir with boiling tap water and drain using said pump;

3. Rinse the reservoir by filling with distilled water and drain with the pump.
 4. Fill the reservoir with a solvent solution and scrub the inner surface of the reservoir with a clean brush;
 5. Drain the reservoir with said pump;
 - 5 6. Rinse the reservoir by filling and draining the reservoir three times with distilled water;
 7. Dry the inside of the reservoir;
 8. Store the reservoir empty and dry overnight;
 9. Change the rubber tube inside the reservoir weekly.
- 10
28. The method of claim 27 wherein said aseptic inflammation of the eye resulting from eye surgery is diffuse lamellar keratitis.
 29. The method of claim 27 wherein said aseptic inflammation of the eye resulting from eye surgery is sterile endophthalmitis.
- 15
30. The method of claim 27 wherein said procedures are carried out less frequently than a daily basis.
 31. The method of claim 27 wherein said procedures are carried out on a quarterly basis.
- 20
32. The method of claim 27 wherein said solvent solution is selected from the group isopropyl alcohol, ethanol, methanol and acetone.
 33. A method for reducing outbreaks of diffuse lamellar keratitis comprising carrying out the method of claim 13 on a daily basis and the method of claim 17 on a less frequent basis.
- 25

34. A method for reducing outbreaks of aseptic inflammations of the eye resulting from eye surgery in eye surgery clinics using a sterilizer for sterilizing medical instruments with steam comprising a housing containing a steam generator supplied by a dispensing pump and a sterilization container for containing said medical instruments, and further comprising a reservoir of distilled water which holds and supplies distilled water to be boiled for the sterilization, said method comprising:

- a) draining the sterilizer's reservoir at the end of each surgical day and using mechanical scrubbing and boiling water treatments prior to and at the end of each surgical day;
- b) placing in the sterilizer at the end of the surgical day a solvent solution, allowing it to evaporate and then treating the reservoir with boiling water.

35. The method of claim 34 wherein said aseptic inflammation of the eye resulting from eye surgery is diffuse lamellar keratitis.

36. The method of claim 34 wherein said aseptic inflammation of the eye resulting from eye surgery is sterile endophthalmitis.

37. The method of claim 34 wherein said solvent solution is selected from the group isopropyl alcohol, ethanol, methanol and acetone.

Abstract of the Disclosure

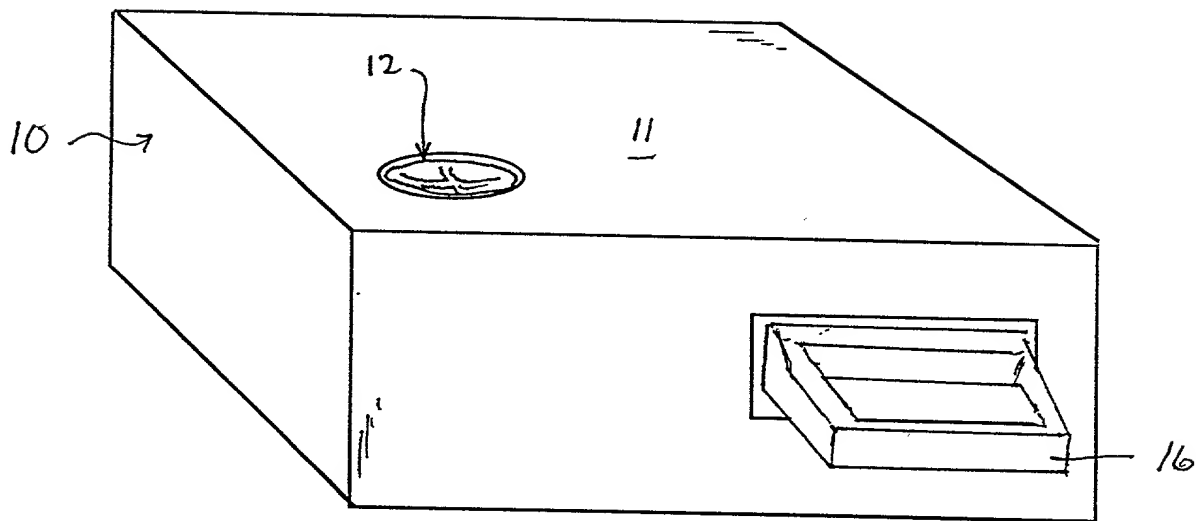
Diffuse lamellar keratitis or DLK is a recently recognised post-surgical condition involving an inflammation that occurs in laser corneal surgery patients.

This condition is typically associated with the LASIK surgical procedure (Laser Assisted In Situ Keratomileusis). The cause is presently unknown. the present invention provides a sterilization apparatus, which may be a retrofitting of the existing sterilizer, which reduces the occurrence of DLK and also methods for maintaining the sterilizer to reduce the occurrence of DLK.

5

10

FIG. 1



1. 2

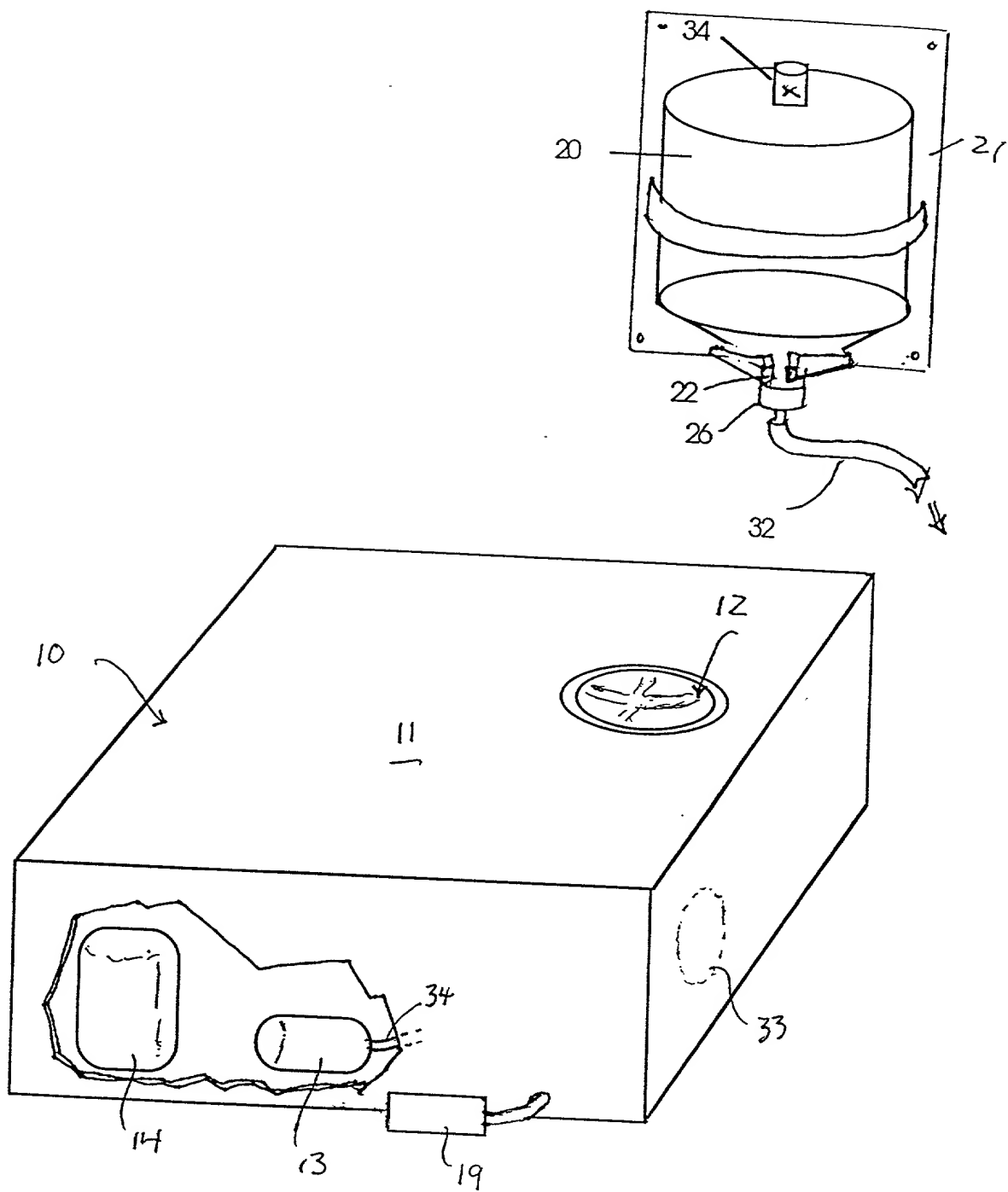


FIG. 2

1

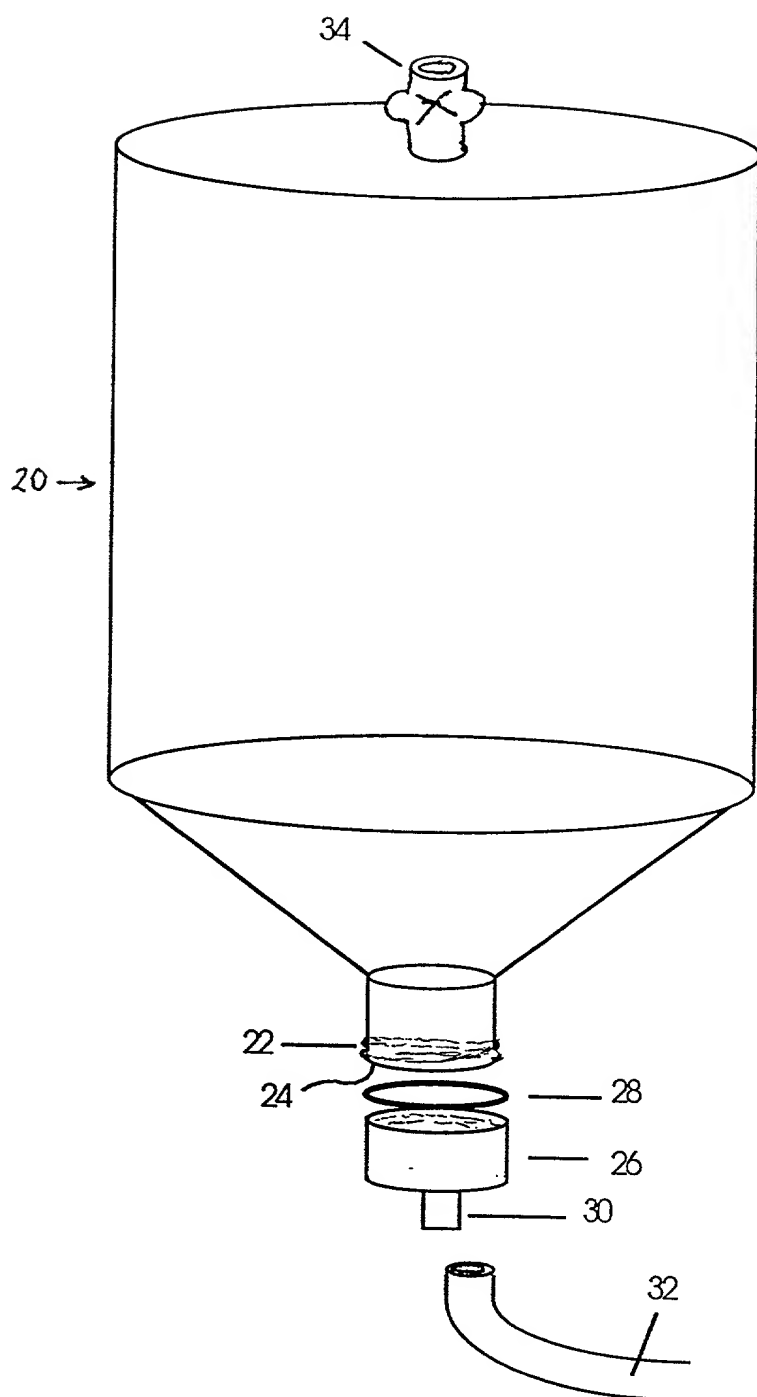


FIG. 3

10

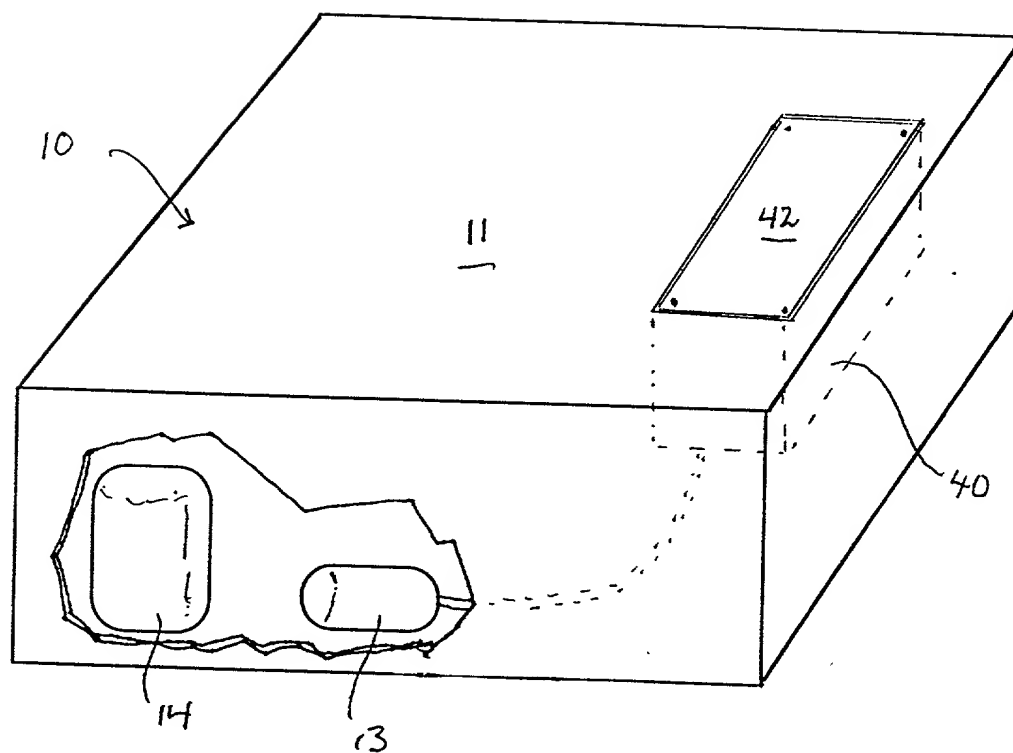


FIG. 4

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the invention entitled:

METHOD AND APPARATUS FOR REDUCING OUTBREAKS OF DIFFUSE LAMELLAR KERATITIS

which is described and claimed in:

- ☒ the attached specification; or,
☐ the specification in application Serial No. _____, filed _____; or,
☐ as amended on _____; or,
☐ PCT international application No. _____ filed _____, as amended under Article 19 on _____ and/or under Article 34 on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge my duty to disclose information which is material to the patentability of this invention in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application on which priority is claimed:

Prior Foreign/PCT Application(s)			Priority Claimed?	
Serial No.	Country	Filing Date	Yes	No
2,287,150	Canada	October 22, 1999	x	

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I hereby claim the benefit, under 35 U.S.C. §119(a)-(d), of any United States provisional application(s) that is/are listed below:

U.S. Provisional Patent Applications	
Serial No.	Filing Date

I hereby claim the benefit, under 35 U.S.C. §120, of any United States application(s) or any PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

U.S. Patent Applications		Status (Check One)		
Serial No.	Filing Date	Patented	Pending	Abandoned

PCT Applications Designating US			Status (Check One)		
PCT No.	Filed	U.S.S.N.	Patented	Pending	Abandoned

I hereby appoint the following attorney(s) and/or agent(s), with full powers of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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Gerald O.S. Oyen	27,280	Thomas W. Bailey	36,411

Parameter	Unit	Value
Initial concentration	mg/L	100
Initial pH		7.0
Temperature	°C	25
Time	h	0, 1, 2, 4, 8, 16, 32, 64, 128, 256, 512, 1024, 2048, 4096, 8192, 16384, 32768, 65536, 131072, 262144, 524288, 1048576, 2097152, 4194304, 8388608, 16777216, 33554432, 67108864, 134217728, 268435456, 536870912, 1073741824, 2147483648, 4294967296, 8589934592, 17179869184, 34359738368, 68719476736, 137438953472, 274877906944, 549755813888, 1099511627776, 2199023255552, 4398046511104, 8796093022208, 17592186044416, 35184372088832, 70368744177664, 140737488355328, 281474976710656, 562949953421312, 1125899906842624, 2251799813685248, 4503599627370496, 9007199254740992, 18014398509481984, 36028797018963968, 72057594037927936, 144115188075855872, 288230376151711744, 576460752303423488, 1152921504606846976, 2305843009213693952, 4611686018427387904, 9223372036854775808, 18446744073709551616, 36893488147419103232, 73786976294838206464, 147573952589676412928, 295147905179352825856, 590295810358705651712, 1180591620717411303424, 2361183241434822606848, 4722366482869645213696, 9444732965739290427392, 18889465931478580854784, 37778931862957161709568, 75557863725914323419136, 151115727451828646838272, 302231454903657293676544, 604462909807314587353088, 1208925819614629174706176, 2417851639229258349412352, 4835703278458516698824704, 9671406556917033397649408, 19342813113834066795298816, 38685626227668133590597632, 77371252455336267181195264, 154742504910672534362390528, 309485009821345068724781056, 618970019642690137449562112, 1237940039285380274899124224, 2475880078570760549798248448, 4951760157141521099596496896, 9903520314283042199192993792, 19807040628566084398385987584, 39614081257132168796771975168, 79228162514264337593543950336, 158456325028528675187087900672, 316912650057057350374175801344, 633825300114114700748351602688, 1267650600228229401496703205376, 2535301200456458802993406410752, 5070602400912917605986812821504, 10141204801825835211973625643008, 20282409603651670423947251286016, 40564819207303340847894502572032, 81129638414606681695789005144064, 162259276829213363391578010288128, 324518553658426726783156020576256, 649037107316853453566312041152512, 1298074214633706907132624082305024, 2596148429267413814265248164610048, 5192296858534827628530496329220096, 10384593717069655257060992658440192, 20769187434139310514121985316880384, 41538374868278621028243970633760768, 83076749736557242056487941267521536, 166153499473114484112975882535043072, 332306998946228968225951765070086144, 664613997892457936451903530140172288, 1329227995784915872903807060280344576, 2658455991569831745807614120560689152, 5316911983139663491615228241121378304, 10633823966279326983230456482242756608, 21267647932558653966460912964485513216, 42535295865117307932921825928971026432, 85070591730234615865843651857942052864, 170141183460469231731687303715884105728, 340282366920938463463374607431768211456, 680564733841876926926749214863536422912, 1361129467683753853853498429727072845824, 2722258935367507707706996859454145691648, 5444517870735015415413993718908291383296, 10889035741470030830827987437816582766592, 21778071482940061661655974875633165533184, 43556142965880123323311949751266331066368, 87112285931760246646623899502532662132736, 174224571863520493293247799005065324265472, 348449143727040986586495598010130648530944, 696898287454081973172991196020261297061888, 1393796574908163946345982392040522594123776, 2787593149816327892691964784081045188247552, 5575186299632655785383929568162090376495104, 11150372599265311570767859136324180752990208, 22300745198530623141535718272648361505980416, 44601490397061246283071436545296723011960832, 89202980794122492566142873090593446023921664, 178405961588244985132285746181186892047843328, 356811923176489970264571492362373784095686656, 713623846352979940529142984724747568191373312, 1427247692705959881058285969449495136382746624, 2854495385411919762116571938898990272765493248, 5708990770823839524233143877797980545530986496, 11417981541647679048466287755595961091061972992, 228359

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Inventor: Douglas W. Morck and Simon P. Holland
Title: **METHOD AND APPARATUS FOR REDUCING
OUTBREAKS OF DIFFUSE LAMELLAR KERATITIS**
Filed: Herewith
Date: March 24, 2000
To: Assistant Commissioner for Patents
Washington, D.C.
20231

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ASSOCIATE POWER OF ATTORNEY

Please recognize the following attorneys as my associate attorneys in respect of this application:

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